

K960963

MAY -6 1996

B. Summary

The Cord Wrap with Needle Resheather (Model CN-34) is an accessory to Infusion Stands, Classification (80 FOX).

As an accessory, it is substantially equivalent to the Ferguson Medical I.V. Hanger Bag or Holder. The 510(k) number for the Ferguson I.V. Hanger Bag or Holder is K883133.

Both the Ferguson Hanger Bag (K883133) and the Osborn Medical Corporation Cord Wrap with Needle Resheather are *accessories* to Infusion Stands.

Submitter:

Osborn Medical Corporation
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Contact Person:

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Trade Name:

Cord Wrap with Needle Resheather

Common Name:

Infusion Stand Accessory

Substantially Equivalent to:

Ferguson Medical I.V. Hanger Bag or Holder

Description of Device:

The Cord Wrap with Needle Resheather comprises a reel for storing electric cords at a pole-type infusion stand. The stand provides a pole stanchion that extends a number of feet and supports an infusion pump and/or bags or bottles of liquid infusants.

Depending on the infusion pump, electric cords extend from the pole. Storage and containment can present difficulties during and between use of the equipment.

The Cord Wrap is constructed to conveniently store the electric cord of the infusion pump at the pole during and between use.

(Photographs in Section E, and drawings in Section F. depict the Cord Wrap with Needle Resheather.)

The cord is coiled about an elongated spool which is retained on the pole via a clamp assembly. The clamp assembly includes a hand wheel and threaded hook arm. The hook arm mounts about the pole, and upon tightening of the hand wheel the hook arm is drawn tight to the infusion stand.

Two protrusions are aligned to the hook arm and form a channel space where the infusion stand can nest. The Cord Wrap with Needle Resheather is thereby prevented from rotating about the pole.

The position of the Cord Wrap with Needle Resheather along the infusion stand can be varied by loosening the hand wheel and moving the Cord Wrap with Needle Resheather either up or down the infusion stand and retightening the hand wheel.

Protruding from the Cord Wrap with Needle Resheather is a needle holder which contains five cavities to receive and retain several cover pieces of needle storage containers.

The Cord Wrap with Needle Resheather is **NOT** a SHARPS RECEPTACLE. Each infusion line set typically requires an infusion needle which is stored in a two-piece container. Each container includes a cover and a needle body.

The five cavities are constructed to receive and hold the cover piece. This permits the staff member to de-couple the needle body from the cover with a single hand.

The Cord Wrap, hand wheel, and Needle Resheather are molded from a resin Acrylonitrile-Butadiene-Styrene (ABS).

The Needle Resheather is glued to the Cord Wrap with Loctite® 494 adhesive.

The threaded hook arm is made of stainless steel.

The Cord Wrap with Needle Resheather is packaged assembled in polyethylene bags.

Twenty-eight Cord Wrap with Needle Resheathers are shipped in standard shipping containers.

Statement of Substantial Equivalence:

Osborn Medical Corporation considers the Cord Wrap with Needle Resheather to be substantially equivalent to the Ferguson Medical I.V. Hanger Bag or Holder.